K072722

APR 24 2008

510(k) Summary
21 CFR 807.92

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

1. Company making the submission:

Company Name:	MEDDORNA, LLC
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Telephone:	(512) 637-2100 Voice (512) 637-2101 Fax
Contact:	Kishor Muzumdar
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2. Device:

Proprietary Name:	MEDDORNA Wireless PRN Spirometer 100
Common Name:	Spirometer
Classification Name:	Diagnostic Spirometer

3. Predicate Devices:

SpiroCard, K973138, QRS Diagnostic, LLC and PMP4 Spiro Pro, K050853, Card Guard Scientific Survival, Ltd., Rehovot 76100, Israel.

4. **Classifications Names & Citations**:

21 CFR 868.1840, Class II, 73 BZG, Anesthesiology.

5. Description:

The MEDDORNA Wireless PRN Spirometer 100 is a full featured spirometer allowing Forced Vital Capacity (FVC) spirometry, Maximum Voluntary Ventilation (MVV), and Slow Vital Capacity (SVC) and all spirometry tests will be available, including pre/post bronchodilator testing.

The MEDDORNA Wireless PRN Spirometer 100 utilizes wireless interface to a thin client Personal Computer or Internet Server. This allows real-time graphical display and review of the spirometry loop along with alpha character patient entry when desired.

The MEDDORNA Wireless PRN Spirometer 100 utilizes pre-calibrated plastic disposable mouthpieces; this negates the need for a 3-liter syringe. The MEDDORNA Wireless PRN Spirometer has a rechargeable battery pack and wireless (Bluetooth) data link output directly to a thin client PC for reporting purposes.

6. Indications for Use:

The MEDDORNA Wireless PRN Spirometer Model 100 is intended for use as a diagnostic spirometer, measuring FVC, MVV and SVC breathing functions.

7. Contra-indications:

None noted at the time of this submission.

8. Comparison:

- Computer Required for Use – MEDDORNA Wireless PRN Spirometer 100 does require a Bluetooth wireless enabled computer for use, whereas the SpiroCard requires a handheld PC without wireless. The PMP4 Spiro Pro utilized Bluetooth wireless to a PDA or PC computer.

- Weight – MEDDORNA Wireless PRN Spirometer and predicate devices weight is similar.

- Dimensions – The MEDDORNA Wireless PRN Spirometer 100 is slightly larger, it has two transducers which allows for more air volume measurements and it has not affected accuracy, testing or precision.

- Off-the-Shelf (OTS) Software required – The SpiroCard requires Window CE to operate. MEDDORNA Wireless PRN Spirometer 100 utilizes Microsoft XP operating system. The MEDDORNA Wireless PRN Spirometer also requires off-the-shelf Bluetooth drivers as does the PMP4 Spiro Pro device.

- Operating Conditions: Humidity – The humidity levels for the MEDDORNA Wireless PRN Spirometer 100 are similar to predicate deives.

- MS Software – The MEDDORNA Wireless PRN Spirometer 100 has no internal static memory. All encrypted data is transferred via Bluetooth wireless to computer as does the PMP4 Spiro Pro device.

9. Test Review:

The MEDDORNA Wireless PRN Spirometer 100 has been tested and found to have the resolution that meets the American Thoracic Standard Pulmonary requirements.

10. Common and Different Features:

The MEDDORNA Wireless PRN Spirometer 100 and predicate devices method of construction are similar. They have the following similarities:

- Indications for Use
- Patient Population
- Safety

- Prescription Device
- EMC
- Labeling

The differences are the following:

- The MEDDORNA Wireless PRN Spirometer 100 and PMP4 Spiro Pro utilize Blue-tooth wireless data link communications to computer the SpiroCard does not.

11. Conclusions:

The conclusion drawn from these tests is that the MEDDORNA Wireless PRN Spirometer is equivalent in safety and efficacy to its predicated devices.

Kishor Muzumdar
Meddorna, LLC

Date: 9/17/2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2008

Meddorna, LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street N.W.
Buffalo, Minnesota 55313

Re: K072722
Trade/Device Name: MEDDORNA Wireless PRN Spirometer 100
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: April 14, 2008
Received: April 15, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number _____

Device Name: MEDDORNA Wireless PRN Spirometer 100.

Indications for Use: The MEDDORNA Wireless PRN Spirometer Model 100 is intended for use as a diagnostic spirometer, measuring FVC, MVV and SVC breathing functions.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072722